



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

April 2, 2024

EA-23-122

Dale Schippers, M.S.
Radiation Safety Officer
Trinity Health Grand Rapids Hospital
200 Jefferson Ave. SE
Grand Rapids, MI 49503

SUBJECT: NOTICE OF VIOLATION; NRC REACTIVE INSPECTION REPORT NO.
03008291/2023001 (DRSS) –TRINITY HEALTH GRAND RAPIDS HOSPITAL

Dear Dale Schippers:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) inspection conducted from February 22 through December 18, 2023, of activities at your Grand Rapids, Michigan facility. The purpose of the inspection was to review the circumstances surrounding the inadvertent shipment of licensed material for disposal at an incinerator facility. An exit meeting was held on December 18, 2023, with you to discuss apparent violations involving the failure to control licensed material and the failure to perform surveys as necessary to comply with NRC disposal requirements. Inspection Report No. 03008291/2023001 (DRSS) was issued on December 21, 2023, and can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML23354A105. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations identified in the report by either attending a pre-decisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated December 29, 2023 (ML24011A067), you and Teresa Lalonde provided a response to the apparent violations.

Based on the information developed during the inspection and the information that you provided in your response to the inspection report dated December 29, 2023, the NRC has determined that two violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The first violation involved the failure to control technetium-99m in a catheter bag that was in an unrestricted area as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1802. The second violation involved the failure to perform surveys, as required by 10 CFR 20.1501, that may be necessary for the licensee to comply with disposal requirements in 10 CFR Part 20. Specifically, the catheter bag was disposed in the normal trash and was sent to an incinerator for disposal. The incinerator facility identified that the catheter contained radioactive material and returned it to Trinity Hospital who then secured the material.

The failure to maintain control and survey licensed material that was not in storage is a significant safety and security concern that resulted in radioactive material exiting the facility. This failure is of regulatory concern due to the release of radioactive material into the public and

the potential unintended exposure to members of the public. Although radioactive material exited the facility without being surveyed, no known exposure to a member of the public occurred. Therefore, these violations have been categorized in accordance with the NRC Enforcement Policy as a Severity Level (SL) III problem. The current Enforcement Policy is included on the NRC's Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$9000 is considered for a SL III problem.

Because your facility has not been the subject of escalated enforcement actions within the last two inspections the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. Credit for corrective actions included: (1) adding a second radiation detector system with two detectors that once triggered, will remain in alarm until a supervisor can reset the detectors; (2) annual training for staff to ensure an appropriate response will take place in accordance with hospital procedures if the radiation detector alarm is heard; and (3) adding a warning statement in patient medical records to notify the nursing staff that processes for patients with radioactive urine will need to be followed.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort. The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 03008291/2023001 (DRSS) and your letter received on December 29, 2023. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response will be made available electronically for public inspection in the NRC Public Document Room and in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such

information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

Sincerely,



Signed by Giessner, Jack
on 04/02/24

John B. Giessner
Regional Administrator

Docket No. 030-08291
License No. 21-01078-01

Enclosure: Notice of Violation

cc: State of Michigan

Letter to D. Schippers from J. Giessner dated April 2, 2024.

SUBJECT: NOTICE OF VIOLATION; NRC REACTIVE INSPECTION REPORT NO.
03008291/2023001 (DRSS) –TRINITY HEALTH GRAND RAPIDS HOSPITAL

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NOTICE OF VIOLATION

Trinity Health Grand Rapids Hospital
Grand Rapids, Michigan

Docket No. 030-08291
License No. 21-01078-01
EA-23-122

During an U.S. Nuclear Regulatory Commission (NRC) inspection conducted February 22 through December 18, 2023, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. Title 10 of the *Code of Federal Regulations* (CFR) 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Contrary to the above, on October 19, 2022, the licensee did not control technetium-99m contaminated waste located in a hospital waste collection area, which is an unrestricted area. Specifically, the contaminated waste was a catheter bag that had been disposed of as normal, non-radioactive, waste.

- B. Title 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

Pursuant to 10 CFR 20.1003, *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

Title 10 CFR 20.2001(a)(1) requires a licensee to dispose of licensed material only by transfer to an authorized recipient as provided in § 20.2006 or in the regulations in part 30, 40, 60, 61, 63, 70, and 72.

Contrary to the above, on October 19, 2022, the licensee did not make surveys to assure compliance with 10 CFR 20.2001(a)(1), which requires a licensee to dispose of licensed material only by transfer to an authorized recipient as provided in § 20.2006 or in the regulations in part 30, 40, 60, 61, 63, 70, and 72. Specifically, the licensee failed to survey hospital waste in accordance with hospital procedures to prevent the licensee from disposing of residual technetium-99m in solid waste through transfer to an unauthorized recipient.

This is a Severity Level III problem (Enforcement Policy Section 6.7).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No.03008291/2023001 (DRSS) and your letter received on December 29, 2023. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply

Enclosure

to a Notice of Violation, (EA-23-122)," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352, and the Document Control Desk, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy or proprietary information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 2nd day of April 2024.